


IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,	)	<b>REDACTED - PUBLIC VERSION</b>
	)	<b>Original Filing Date: September 25, 2023</b>
Plaintiff,	)	<b>Redacted Filing Date: October 2, 2023</b>
	)	
v.	)	C.A. No. 21-1015 (GBW)
	)	
SAREPTA THERAPEUTICS, INC.,	)	
	)	
Defendant.	)	
<hr/>		
SAREPTA THERAPEUTICS, INC. and THE	)	
UNIVERSITY OF WESTERN AUSTRALIA,	)	
	)	
Defendant/Counter-Plaintiffs,	)	
	)	
v.	)	
	)	
NIPPON SHINYAKU CO., LTD.	)	
and NS PHARMA, INC.	)	
	)	
Plaintiff/Counter-Defendants.	)	

**SAREPTA THERAPEUTICS, INC. AND THE UNIVERSITY OF  
WESTERN AUSTRALIA’S REPLY BRIEF IN SUPPORT OF THEIR  
MOTION TO BIFURCATE AND STAY ANTITRUST COUNTERCLAIM**

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## I. INTRODUCTION

The court should grant Sarepta's motion—and reject NS's arguments—for three reasons.

First, NS's assertion that Sarepta has all of the discovery it needs is wrong. NS first asserted its antitrust counterclaim *after the close of discovery*, giving Sarepta *zero* opportunity to take discovery on those claims. Contrary to NS's arguments, its antitrust counterclaim does require reopening fact discovery to allow Sarepta to develop evidence necessary to its defense. Indeed, NS's own antitrust expert report makes assumptions, conclusory statements, and damages estimations that can only be tested with additional party and third party discovery. None of that discovery has occurred—nor could it—because NS's antitrust counterclaim was not yet “a party's claim or defense” in this case while discovery was ongoing.

Second, Sarepta will be unfairly prejudiced—and the jury will be even more confused—if NS's antitrust claims are tried alongside the patent claims. This is already an unusually complex patent infringement case, involving ten patents on the incredibly-complicated and technical exon-skipping antisense oligonucleotide technology being asserted in both directions. The patent issues on their own would be challenging for a lay jury to understand; interjecting antitrust allegations would make the situation that much worse. Courts in this district have repeatedly recognized that injecting complex antitrust issues into already complex patent cases raises serious concerns of juror confusion—yet that is exactly what NS proposes to do.

Third, severing the antitrust counterclaim will significantly promote judicial efficiency. NS's *Walker Process* claim relies on Sarepta's decision to assert its allegedly fraudulent patents by bringing the compulsory counterclaims that will be adjudicated at the patent trial. As such, a finding that Sarepta's patents are valid and infringed would dispose of NS's antitrust claims.

## II. ARGUMENT

### A. NS's Expert Report Confirms That Proceeding on the Antitrust Claims Without Discovery Will Severely Prejudice Sarepta

Sarepta is eager to proceed to trial on the patent claims in this litigation, which has been pending since NS instigated the litigation in 2021. But NS's own antitrust expert report confirms that *it is not possible to defend against NS's antitrust claims without reopening discovery which would completely upend the parties' trial schedule.*

As an initial matter, NS's assertion that Sarepta already has all the discovery it needs is demonstrably wrong. D.I. 356 at 6-7. NS suggests that it was pursuing discovery relevant to its antitrust claims all along *sub silentio*, and that Sarepta is at fault for not serving any additional discovery after August 3, 2023, when the Court allowed NS's antitrust counterclaims to proceed. D.I. 356 at 7. But fact discovery closed on July 27, 2023 and the parties specifically stipulated on July 18 that they would not "serve any new written discovery that has not been served as of June 27, 2023." D.I. 269 at 2. Despite apparently conducting antitrust-related discovery for its own use, NS failed to supplement its Rule 26 disclosures to account for its antitrust counterclaims, and never alerted Sarepta that it was proceeding as if antitrust discovery were underway.<sup>1</sup> According to NS, Sarepta was apparently supposed to guess that it would need discovery to defend against a claim that simply did not exist at the time. That is not how discovery is supposed to work. *See* Fed. R. Civ. P. 26(b)(1) ("Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's *claim or defense* . . .") (emphasis added). The antitrust claim was not in the case, so Sarepta did not take discovery on it. To the extent NS believes it has obtained the

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<sup>1</sup> For this same reason, the Court should not credit NS's complaint that it will be prejudiced because it has already served its antitrust expert report. D.I. 356 at 15.

discovery it needs, that reflects its strategic decision to quietly seek discovery relevant to its antitrust claims between the time Sarepta raised its counterclaims and the close of discovery.

NS is also wrong that any discovery needed for its antitrust counterclaim is within Sarepta's control. *See* D.I. 356 at 7. NS myopically focuses on only one element of its claim—that Sarepta allegedly procured the UWA patents through fraud. That element—and that element alone—may be somewhat cumulative to the inequitable conduct claim. But the *other* required elements of its antitrust counterclaim are not. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. None of this evidence is exclusively within Sarepta's control, as NS's own expert report demonstrates.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Similarly, Sarepta will need third-party discovery to test NS's alleged relevant antitrust market. The "relevant market" is a term of art in antitrust law different from the "market" that has been the focus of the patent case to date. *See Bio-Rad Lab's, Inc. v. 10X Genomics, Inc.*, 483 F. Supp. 3d 38, 56-57 (D. Mass. 2020) (distinguishing "market definition for patent infringement" purposes, which considers "whether the two parties were direct competitors," and market definition for antitrust purposes, which considers "whether their products were reasonably interchangeable with potential outside substitutes"); *see also* Herbert Hovenkamp, Markets in IP and Antitrust, 100 Geo. L.J. 2133, 2141-43 (2012) (discussing the differences in market delineation between intellectual property and antitrust law). In particular, Sarepta needs discovery that will allow it to test [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Although he brushes these competitors aside, there has been no discovery into the actual timelines for entry or these companies' plans to compete with Sarepta or other providers of DMD therapies. *See Pfizer Inc. v. Johnson & Johnson*, No. 17-CV-4180, 2018 WL 1071932, at \*2 (E.D. Pa. Feb. 27,

2018) (granting stay of discovery in antitrust suit until resolution of motion to dismiss because “the scope of discovery in this case will likely be enormous,” including discovery from “various third parties”). And third-party discovery on future entry—necessary in attempted monopolization cases—is distinct from the kind of discovery NS and Sarepta conducted in the patent case. *See Crossroads Cogeneration Corp. v. Orange & Rockland Utilities, Inc.*, 159 F.3d 129, 141 (3d Cir. 1998) (“probable development of the industry” is relevant to evaluating threat of monopolization because “[a]lleging market share alone is not sufficient” to show monopoly power).

Finally, NS ignores the fact that it has produced no discovery regarding its claimed antitrust damages. Instead, NS asserts incorrectly that the “pricing of the parties’ products” is the information “necessary to assess[] antitrust damages.” D.I. 356 at 6-7. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Again, due to NS’s failure to supplement its initial disclosures, and the close of fact discovery before the Court allowed NS’s counterclaims to proceed, Sarepta has had no opportunity to cross-examine these witnesses or to test any of the assertions that Dr. Maness makes in his report. Sarepta should not have to choose between resolving the patent litigation on the schedule that has been in place for nearly a year and vigorously defending against NS’s baseless and distracting counterclaims. *See* D.I. 124.

**B. NS’s Antitrust Claims Will Lead to Juror Bias and Confusion**

NS admits that it intends to present evidence to the jury of Sarepta’s purported “predatory conduct.” *See* D.I. 356 at 7. However, the “predatory conduct” that NS alleges is *Sarepta’s*

*decision to bring compulsory infringement counterclaims against NS after NS commenced this litigation.* D.I. 324 ¶¶ 106-07. Assertions that Sarepta is a bad actor because it filed the same infringement counterclaims the jury is being asked to resolve will bias and confuse the jury and prevent Sarepta from getting a fair trial on its patent claims. The risk of juror confusion and bias from presenting such evidence is precisely the type of prejudice courts in this district have sought to avoid when bifurcating patent and antitrust claims. *See* D.I. 346 at 6 (Opening Br.); *Masimo Corp. v. Philips Elecs. N. Am. Corp.*, C.A. No. 09-80-JJF-MPT, 2010 WL 925864, at \*2 (D. Del. Mar. 11, 2010) (noting that “allegations of monopolization could bias the jury when it evaluates [the patentee]’s patent claims.”); *Invidi Tech. Corp. v. Visible World Inc.*, C.A. No. 11-397, D.I. 172, at 2 (D. Del. Dec. 7, 2012) (Ex. 2) (trifurcating “potentially prejudicial” antitrust and related state law claims from patent infringement claims).

With respect to juror confusion, NS attempts to distinguish Sarepta’s litany of analogous cases on the basis that “there are not such unusually high numbers of patents asserted” in this case. *See* D.I. 356 at 10. But this case involves accusations of infringement by different products from different companies and ten patents, each of which involves unusually complex technology (even for a patent case). The technology at issue in this case is not, for example, a mechanical invention that can be readily understood by comparing patent figures to pictures or diagrams of the accused product. “Antisense oligonucleotides,” “exon skipping,” and “human dystrophin pre-mRNA” are not terms the average lay juror will find at all accessible, and are generally the province of professors and career scientists. Thus, the technology alone will already be extremely difficult for the jury to comprehend, and resolving the patent claims alone will require jurors to understand complex issues of infringement and validity related to each of the ten asserted patents. Adding antitrust issues would make the case all that much more complex and confusing. This is precisely

why courts in this district have recognized that adding antitrust claims into already “complicated legal concepts and technologies at issue in patent infringement and validity disputes” would only “magnif[y]” the confusion in such a trial. *See Eurand Inc. v. Mylan Pharms. Inc.*, C.A. No. 08-889-SLR, 2009 WL 3172197, at \*1 n.4 (D. Del. Oct. 1, 2009)<sup>2</sup>; *see also* D.I. 346 at 7. Indeed, even outside the context of antitrust issues, courts in this district routinely bifurcate issues to avoid juror confusion. *See, e.g., ViaTech Tech. Inc. v. Microsoft Corp.*, C.A. No. 14-1226, D.I. 134, at 1 (D. Del. June 6, 2016) (Ex. 3) (bifurcating cross-asserted patent claims into two separate trials “in order to avoid jury confusion” where the plaintiff and defendant each only asserted one patent against the other); *Analog Devices, Inc. v. Xilinx, Inc.*, C.A. No. 19-2225-RGA, Pretrial Conf. Tr., at 6:5-8:24 (D. Del. Feb. 7, 2020) (Ex. 4) (bifurcating each party’s patent infringement claims and noting that “[t]he presumption is separate trials”); *British Telecomm’ns PLC v. Google Inc.*, C.A. No. 11-1249-LPS, 2013 WL 3814329, at \*2 (D. Del. July 22, 2013) (bifurcating damages from liability at trial “will reduce the risk of juror confusion”).

Contrary to NS’s assertions,<sup>3</sup> bifurcating the antitrust claim would not “set an unworkable precedent.” Rather, it would be in line with the many cases bifurcating complex issues to avoid juror confusion. As the Federal Circuit has recognized, bifurcation will “*enhance the parties’* right

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<sup>2</sup> Although NS attempts to distinguish *Eurand* on the basis that the motion to bifurcate was not opposed (D.I. 356 at 10), this does not address the actual substance of the court’s reasoning. A court’s analysis of the bifurcation factors, including juror confusion, is still directly relevant to the instant case, regardless of whether the motion was opposed or not.

<sup>3</sup> NS’s reliance on *EIS, Inc. v. WOW Tech. Int’l* is misplaced for several reasons. First, the court did not rule on defendants’ “alternative” request to bifurcate in their summary judgment brief. *See* C.A. No. 19-1227-GBW, D.I. 430 at 38 (D. Del. May 19, 2023); *see generally id.*, D.I. 606 & 607. Further, there were only five patents asserted in *EIS*, and the patents involved simple mechanical devices, not complex biotechnology as in this case. *See id.*, D.I. 111 (Third Amended Complaint). Moreover, the antitrust claim there was asserted four years before trial (*see id.*, D.I. 9 (First Amended Complaint)) and was in the case throughout fact and expert discovery.

to jury trial by making the issues the jury must consider less complex.” *See In re Innotron Diagnostics*, 800 F.2d 1077, 1086 (Fed. Cir. 1986) (emphasis added).

**C. NS Ignores the Immense Judicial Efficiency of Bifurcation and a Stay**

NS’s argument that proceeding with the antitrust counterclaims promotes judicial efficiency simply assumes that it will win on every count. D.I. 356 at 12-13. NS, however, ignores that a finding of validity of UWA’s patents would moot, or at the very least narrow, the antitrust count. *See* D.I. 346 at 9-11; *Fresenius Kabi USA, LLC v. Fera Pharms., LLC*, C.A. No. CV-15-3654-KM-MAH, 2017 WL 2213123, at \*4 (D.N.J. May 19, 2017) (severing and staying discovery as to *Walker Process* counterclaim because if the asserted patents were found to be valid and infringed, the antitrust claim “would likely be mooted; enforcement of a valid patent does not generally violate the antitrust laws”).<sup>4</sup> This is because NS’s *Walker Process* claim relies on Sarepta’s decision to assert its allegedly fraudulent patents by bringing the compulsory counterclaims that will be adjudicated at the patent trial. If the jury finds that UWA’s patents are valid and infringed, NS can no longer claim that Sarepta unlawfully asserted those valid patents against NS. *See Eagle Pharms., Inc. v. Eli Lilly & Co.*, No. 17-cv-6415, 2018 WL 3492145, at \*6 (D.N.J. July 20, 2018). In other words, the invalidity or unenforceability of Sarepta’s patents are a necessary, but not sufficient, element of NS’s antitrust claim.

Additionally, the “overlap” of evidence related to any alleged fraudulent procurement of the UWA patents demonstrates that the first trial has the ability to significantly narrow or moot the

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<sup>4</sup> Although NS suggests that its unenforceability allegations present an issue separate from validity, that is incorrect. NS’s inequitable conduct claims require a showing that UWA failed to provide or misled the examiner with information which, if known, would render the patent invalid. Thus, unless NS proves to the jury that the patent is invalid in view of that information, NS’s inequitable conduct claim fails for lack of materiality. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1292 (Fed. Cir. 2011) (noting that “but-for materiality generally must be proved to satisfy the materiality prong of inequitable conduct”).

second trial, which further promotes judicial efficiency. *See* D.I. 346 at 10; *Masimo*, 2010 WL 925864, at \*2 (“The court’s interest in efficiency also weighs in favor of bifurcation . . . . A trial will determine, at the very least, the validity and scope of Masimo’s asserted patents, and the scope of Masimo’s patent protection may affect its liability under antitrust laws.”). Indeed, NS ignores that even an invalidity finding may moot the antitrust count, depending on the jury’s factual findings and the basis for invalidity. By the same token, a finding of invalidity could narrow the issues for any subsequent antitrust trial, significantly streamlining that proceeding.

In any event, NS ignores that a separate antitrust trial will not be a complete duplication of the patent trial with simply different ultimate questions for the jury. A separate antitrust trial would not require repetition of the detailed, complex technology required for the trial on patent infringement and validity. Instead, the jury would only need to consider the three UWA patents at issue, the circumstances surrounding Sarepta’s procurement of those patents, and evidence regarding the additional antitrust elements of NS’s attempted monopolization claim.

For the above reasons, NS failed to articulate any actual prejudice to it if the Court bifurcated and stayed the antitrust counterclaim. Although NS argues that it will be prejudiced if “Sarepta is able to continue to proceed with a lawsuit based on fraudulently acquired patents thereby causing NS to incur attorneys’ fees and face unlawful market conditions,” D.I. 356 at 8, the patent lawsuit, which includes NS’s first-filed patent claims against Sarepta, will continue regardless of whether NS’s antitrust counterclaim is heard at the same trial or a slightly later one. Thus, NS will be paying attorneys’ fees and its executives will be spending time to litigate patent claims whether the claims are presented in a single trial or whether the antitrust trial occurs separately at a later date. Importantly, should Sarepta prevail, NS will not be entitled to attorneys’

fees or other damages at all. And if, hypothetically, NS ultimately prevails on its (baseless) antitrust counterclaim, it can be made whole at that time.

NS relies heavily on decisions from district courts in other circuits for the assertion that “[t]here is no universal practice of bifurcating and staying antitrust claims from patent claims in infringement cases.” D.I. 356 at 5 (quoting *Procter & Gamble Co. v. CAO Grp., Inc.*, No. 1:13-CV-337, 2013 WL 6061103, at \*2 (S.D. Ohio Nov. 18, 2013)). As courts in this district have recognized, however, the “Federal Circuit’s general guidance [is] that antitrust issues should typically be bifurcated in patent cases.” *Orthophoenix, LLC v. Dfine, Inc.*, C.A. No. 13-1003-LPS, 2015 WL 1938702, at \*1 (D. Del. Apr. 28, 2015); *see also Masimo*, 2010 WL 925864, at \*1 (“Bifurcation of patent and antitrust claims is not mandatory, but is common.”). Judge Sleet’s opinion in *Synopsys, Inc. v. Magma Design Automation*, C.A. No. 05-701 (GMS), 2006 WL 1452803 (D. Del. May 25, 2006), does not undermine the guidance provided by those myriad cases. *See id.* at \*4 (explaining that “the routine practice of other courts may indicate that ‘experience has demonstrated [the] worth’ of bifurcation in these circumstances”). That decision stands for the unremarkable point that decisions to bifurcate should be based “first and foremost [on] the merits of th[e] case.” *Id.* at \*4. That is consistent with Sarepta’s position. The antitrust portion of this case is in its *earliest possible stage* (indeed, NS’s motion to amend was granted a mere eight weeks ago). There has been no discovery in the antitrust case. The circumstances of *this case* favor bifurcation, a conclusion other courts have reached in similar circumstances. *See generally* D.I. 346. The Court should reach the same result here.

### III. CONCLUSION

Sarepta respectfully requests that the Court grant its motion to bifurcate and stay NS’s antitrust counterclaim pending the jury trial on the underlying infringement and invalidity claims.

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**CERTIFICATE OF SERVICE**

I hereby certify that on September 25, 2023, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on September 25, 2023, upon the following in the manner indicated:

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